REMARKS

Claims 1, 5, 6, 12, 13, 15-18, 20-23, 31, 32 and 34-37 are pending in the present application. Claims 1, 18, 31, and 34 are amended herein. No new matter has been added by these amendments. Upon entry of this response, claims 1, 5, 6, 12, 13, 15-18, 20-23, 31, 32 and 34-37 will be pending.

The Rejections Under 35 U.S.C. § 102(e) Should Be Withdrawn

Claims in the present application are rejected under 35 U.S.C. § 102(e) over several references. Applicant traverses each rejection in turn below.

The Rejection Over Strom

Claim 1 remains rejected under 35 U.S.C. § 102(e) as allegedly anticipated by Strom *et al.*, U.S. Publ. No. 2003/0235563 ("Strom"). Office Action at pages 3-4.

The Office Action contends that the Applicant's previous response is unpersuasive because the amendment to claim 1 allegedly "requires that the plurality of potent cells includes *all* of the cell types listed," referring to the language "$CD34^-$, $OCT\text{-}4^+$, $SSEA3^-$, $CD10^+$, $CD29^+$, $CD38^-$, $CD44^+$, $CD45^-$, $CD54^+$, $CD90^+$, $SH2^+$, $SH3^+$, $SH4^+$, $SSEA4^-$, and $ABC\text{-}p^+$" (emphasis in original). Office Action, at page 4. Applicant submits that this language clearly refers to one type of cell, not different cell types.

However, in the interest of clarity and furthering prosecution, claim 1 has been amended herein to specify that the potent cells in the claimed cytotherapeutic unit comprises *cells that are* $CD34^-$, $OCT\text{-}4^+$, $SSEA3^-$, $CD10^+$, $CD29^+$, $CD38^-$, $CD44^+$, $CD45^-$, $CD54^+$, $CD90^+$, $SH2^+$, $SH3^+$, $SH4^+$, $SSEA4^-$, and $ABC\text{-}p^+$. As such, claim 1 clearly requires that the recited cells have this marker profile, the marker profile recited in previously-pending claim 54. Strom does not teach or suggest placental stem cells that have this marker profile. As such, claim 1 as amended is novel in view of the Strom.

The Rejection Over Casper

Claims 1, 5, 6, 12, 13, 15-18, 20-23, 31, 32, and 34-37 remain rejected under 35 U.S.C. § 102(e) as allegedly anticipated by Casper *et al.*, U.S. Publ. No. 2005/0074435 ("Casper"). Office Action at pages 4-6.

The Office Action contends that the Applicant's previous response is unpersuasive allegedly because claims 1, 18, 31 and 34 as amended allegedly "require that the plurality of potent

cells includes *all* of the cell types listed," referring to the language "$CD34^-$, $OCT\text{-}4^+$, $SSEA3^-$, $CD10^+$, $CD29^+$, $CD38^-$, $CD44^+$, $CD45^-$, $CD54^+$, $CD90^+$, $SH2^+$, $SH3^+$, $SH4^+$, $SSEA4^-$, and $ABC\text{-}p^+$" (emphasis in original). Office Action, at page 4. Applicant submits that this language clearly refers to one type of cell, not different cell types.

However, in the interest of clarity and furthering prosecution, claims 1, 18, 31 and 34 have been amended herein to specify that the potent cells in the claimed cytotherapeutic unit comprises *cells that are* $CD34^-$, $OCT\text{-}4^+$, $SSEA3^-$, $CD10^+$, $CD29^+$, $CD38^-$, $CD44^+$, $CD45^-$, $CD54^+$, $CD90^+$, $SH2^+$, $SH3^+$, $SH4^+$, $SSEA4^-$, and $ABC\text{-}p^+$. As such, claim 1 clearly requires that the recited cells have this marker profile, which was recited in previously-pending claims 54-57, which were not rejected on this basis.

Moreover, the Office Action contends that "Casper et al teach . . . a plurality of potent cells (i.e., CD34+ and OCT-4+ cells and SSEA4+ cells and SSEA3+ cells and SSEA3- cells and CD34- cells) . . . ." citing Casper, paragraph [0023]. Respectfully, this statement is not correct. Casper, paragraph [0023] discloses only that antibodies may be used to detect whether certain specifically-listed markers are present, and does not disclose that those markers are necessarily present or absent on the cells disclosed therein. The Office Action also cites Casper claims 1-3 and 14. Only claim 14 of Casper lists any markers. Claim 14 specifies cells that, *inter alia*, are $CD45^+$ (part (a)) and "express embryonic stem cell proteins" (part (h)). Embryonic stem cells are defined in paragraph [0121] of Casper as expressing SSEA3 and SSEA4, that is, as being $SSEA3^+$ and $SSEA4^+$. As such, Casper discloses cells that are, *inter alia*, $CD45^+$, $SSEA3^+$ and $SSEA4^+$. The isolated cells recited in the amended claims, in contrast, are $CD45^-$, $SSEA3^-$ and $SSEA4^-$. The Office Action cites Erices *et al.*, *Br. J. Haematology*, 109(1):235-242 (2000) and Edinger *et al.*, U.S. Publ. 2007/0275362 ("the '362 publication") allegedly as evidence that "the placental stem cell compositions of Casper et al. would inherently contain each of the claimed cell types." Office Action at page 6. However, neither Erices nor the '362 application provide evidence that Casper teaches the isolated cells recited in the amended claims. As such, for this additional reason, Casper does not anticipate the amended claims.

For at least the above reasons, claims 1, 18, 31, and 34 as amended are novel over Casper. Moreover, because claims 5, 6, 12, 13, 15-17, 20-23, 32 and 35-37 depend from claim 1, 18, 31, or 34, these claims are also novel over Casper. Withdrawal of this rejection of the claims is therefore respectfully requested.

The Rejection Over Edinger

Claims 1, 5, 6, 12, 13, 15-18, 20-23, 31, 32, and 34-37 are newly-rejected under 35 U.S.C. § 102(e) as allegedly anticipated by the '362 publication". Office Action at pages 6-7.

35 U.S.C. § 102(e) states that "[a] person shall be entitled to a patent unless . . . (e) the invention was described in (1) an application for patent, published under section 122(b), *by another* . . ." Inventorship of the '362 publication, filed as U.S. Patent Application No. 11/648,813, was amended on November 17, 2008 by a Request under Rule 48 to specify that the sole inventor of the subject matter claimed therein is Robert J. Hariri. Robert J. Hariri is also the sole inventor of the subject matter claimed in the present application. As such, Application No. 11/648,813, and thus the '362 publication, is not an "application for patent . . . by another". The '362 publication is therefore not available as art under 35 U.S.C. § 102(e).

Moreover, Applicant notes that the isolated cells recited in amended claims 1, 18, 31 and 34 are not specifically disclosed in the '362 publication in the cited paragraphs ([0064], [0085], [0091] and [0157]). As amended, claims 1, 18, 31 and 34 specify isolated cells that are $CD34^-$, $OCT\text{-}4^+$, $SSEA3^-$, $CD10^+$, $CD29^+$, $CD38^-$, $CD44^+$, $CD45^-$, $CD54^+$, $CD90^+$, $SH2^+$, $SH3^+$, $SH4^+$, $SSEA4^-$, and $ABC\text{-}p^+$. As such, the '362 publication does not anticipate the rejected claims.

For at least the above reasons, withdrawal of this rejection of the claims is respectfully requested.

The Provisional Double Patenting Rejection Should Be Withdrawn

Claims 1, 5, 6, 12, 13, 15-18, 20-23, 31, 32 and 34-37 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 71-93 of copending U.S. Application No. 11/592,544. Office Action, at pages 7-8. Applicant traverses as follows.

The Manual of Patent Examining Procedure ("MPEP") states that "[i]f a 'provisional' nonstatutory obviousness-type double patenting (ODP) rejection is the only rejection remaining in the earlier filed of the two pending applications, while the later-filed application is rejectable on other grounds, the examiner should withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer." *See* MPEP § 804(I)(B)(1), at page 800-17. The present application was filed earlier than application 11/592,544. It is believed that the pending claims, as currently amended, overcome the pending 35 U.S.C. § 102(e) rejections. As Applicant

estimates that upon entry of the present Amendment, this provisional double patenting rejection will be the only rejection remaining in the present application, Applicant respectfully requests that this provisional rejection be withdrawn.

CONCLUSION

Applicant respectfully requests that the present amendments and remarks be made of record in the file history of the present application. An early allowance of the application is earnestly requested. Applicant estimates that a fee of $810.00 for Request for Continued Examination is due. The fees will be paid by EFS-Web at the time this paper is filed. Applicant believes that no other fees are due. However, if any fees should be deemed due, please charge such fees to Jones Day deposit account no. 503013, referencing our number 501872-999494. The Examiner is invited to contact the undersigned with any questions concerning the application.

Respectfully submitted,

Date: December 14, 2010

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